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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/986,634	11/09/2001	Marc Alizon	3495.0104-03	5658

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP
1300 I STREET, NW
WASHINGTON, DC 20005

EXAMINER

PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 10/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/986,634

Applicant(s)

ALIZON ET AL.

Examiner

J. Parkin

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-29 is/are pending in the application.
- 4a) Of the above claim(s) 16-21 and 26-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 06/835,228.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Serial No.: 09/986,634
Applicants: Alizon, M., et al.

Docket No.: 3495.0104-03
Filing Date: 11/09/01

Detailed Office Action

Status of the Claims

1. Applicants' election of Group II (claims 22-25) in paper no. 8 is acknowledged. Because applicant did not distinctly and specifically point out the purported errors in the restriction requirement, the election has been treated as an election without
5 traverse (refer to M.P.E.P. § 818.03(a)). Claims 16-21 and 26-29 are withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention. claims 22-25 are currently under examination.

Title/Abstract

10 2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: METHODS FOR PRODUCING POLYPEPTIDES FROM HIV-2 CDNAS.

15 3. The abstract of the disclosure is objected to because it fails to describe the salient characteristics of the claimed invention. Applicants are reminded of the proper content of an Abstract of the Disclosure pursuant to § 608.01(b) of the M.P.E.P. An appropriate
20 abstract will be suggested by the Examiner when allowable subject matter has been identified.

Information Disclosure Statement

25 4. The information disclosure statement filed 06 February, 2002, has been placed in the application file and the information referred to therein has been considered.

35 U.S.C. § 112, Second Paragraph

5. Claims 22-25 are rejected under 35 U.S.C. § 112, second

paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is vague and indefinite in referencing an HIV-2 cDNA and deposited fragments, as well as, various hybridization parameters. The claims appear to be directed toward the production of polypeptide fragments produced from nucleic acid fragments of the full-length viral genomic cDNA clone which has the C.N.C.M. accession no. I-627 (pROD 4.7). The reference to the hybridization parameters is confusing because it is not readily manifest if the claims are supposed to encompass other related, but genotypically distinct, sequences of the proviral genomic clone or if they are simply reciting another characteristic of fragments obtained from the cDNA clone. Appropriate correction and clarification are required (i.e., A method of producing an HIV-2 polypeptide comprising the following steps: I) obtaining a nucleic acid fragment of the viral genomic clone having the C.N.C.M. accession no. I-627; ii) cloning said fragment into a suitable recombinant expression vector; iii) expressing the HIV-2 polypeptide encoded by said fragment; and iv) isolating and recovering the polypeptide).

35 U.S.C. § 112, First Paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 22-25 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In *re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). In *re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976).

5 To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Vas-*
Cath, Inc., v. Mahurkar, 935 F.2d at 1563, 19 U.S.P.Q.2d at 1116.

10 The issue raised in this application is whether the original application provides adequate support for the broadly claimed genus of polypeptides, and fragments thereof, encoded by a series of cDNA fragments from the viral clone having the C.N.C.M. accession no. I-
627 (pROD 4.7). An applicant shows possession of the claimed

15 invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565,
1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997). The claimed

20 invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only

25 by functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the biomolecule of interest. In *re Bell*, 991 F.2d

30 781, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1993). In *re Deuel*, 51 F.3d 1552, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995). A lack of adequate written description issue also arises if the knowledge and level of

skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 U.S.P.Q.2d 1895, 1905 (Fed. Cir. 1995). The court noted in this
5 decision that a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not reasonably lead those skilled in the art to any particular species.

An applicant may show possession of an invention by disclosure
10 of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant
15 was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. For some biomolecules, examples of
20 identifying characteristics include a nucleotide or amino acid sequence, chemical structure, binding affinity, binding specificity, and molecular weight. The written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation
25 between structure and function. Without such a correlation, the capability to recognize or understand the structure from the mere recitation of function and minimal structure is highly unlikely. In the latter case, disclosure of function alone is little more than a wish for possession; it does not satisfy the written
30 description requirement. *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 U.S.P.Q.2d 1398, 1404, 1406 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089 (1998). In re

Wilder, 736 F.2d 1516, 1521, 222 U.S.P.Q. 369, 372-3 (Fed. Cir. 1984). Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention.

The deposited nucleic acid bearing the accession no. I-627 (pROD 4.7) is a full-length viral genomic clone of HIV-2_{ROD} that was obtained from a circular DNA form. A restriction map or the nucleotide sequence of this 9.5 kb clone was not provided. Attendant open reading frames and their amino acid sequences were not set forth. Thus, the coding potential of the pROD 4.7 insert remains to be elucidated. It is quite feasible, considering the quasispecies nature of HIV-1 and -2, that said sequence is defective in one or more locations and replication-impaired. The disclosure describes the preliminary cloning and characterization of a novel HIV-2 retrovirus. A small number of clones were generated and preliminary restriction maps and sequence data was obtained. No such data was provided for I-627. There is a single example in the disclosure providing a generic discussion of how to prepare DNA probes for use in diagnostic kits. However, the disclosure clearly fails to identify a single HIV-2 protein, or fragment thereof, and suitable pROD 4.7 nucleic acid fragments that are capable of encoding said proteins. Accordingly, the skilled artisan would reasonably conclude that applicants were not in possession of the claimed invention at the time of filing. Clearly this is an attempt by applicants to obtain subject matter to which they are not entitled.

Correspondence

8. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers

5 must conform with the notice published in the Official Gazette,
1096 OG 30 (November 15, 1989). Official communications should be
directed toward the following Group 1600 fax number: (703) 872-
9306. Any inquiry concerning this communication should be directed
to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-
2227. The examiner can normally be reached Monday through Thursday
from 8:30 AM to 6:00 PM. A message may be left on the examiner's
voice mail service. If attempts to reach the examiner are
unsuccessful, the examiner's supervisors, Laurie Scheiner or James
10 Housel, can be reached at (703) 308-1122 or (703) 308-4027,
respectively. Any inquiry of a general nature or relating to the
status of this application should be directed to the Group 1600
receptionist whose telephone number is (703) 308-0196.

Respectfully,



Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

30 September, 2003